

**REMARKS**

Claims 1 and 26-48 are pending.

Claims 2-25 were previously cancelled.

Claims 30-47 are cancelled with entry of this amendment.

Claims 1, 26-29 and 48 are currently under consideration with entry of this amendment.

Claims 49-65 are new.

Pursuant to the Examiner's suggestions during a telephonic interview on November 6, 2003, Applicants have amended the claims with the intention of overcoming the cited prior art and placing the claims in a condition for allowance.

**Support for Amendments to Claims**

Claim 1 has been amended to recite a method for treating a disease comprising "providing a drug delivery unit having a **volume of between 0.1 to 250 mm<sup>3</sup>**." The volume limitation is supported in the application at page 42, lines 20-24. Particularly, the recited range of volumes can readily be calculated from the length and diameter values taught in the application using the formula for the volume of a cylinder (volume =  $L \times \pi \times r^2$ ). Applicants wish to point out that the recited volumes may be translated to all other shapes associated with the drug delivery unit of the present invention and they are not intended as a limitation to a cylindrical shape. (see application at page 42, lines 28-33).

Amended claim 1 also now recites a "synthetic carrier release material adapted for delivery of a therapeutic agent **in nanogram to microgram quantities**." This limitation is supported in the application at page 8, lines 17-19.

Claim 29 has been amended to recite a limitation "wherein said therapeutic agent is present in a **quantity of 10 to 40 wt%** of the total weight of the drug delivery unit." This limitation is supported in the application at page 40, lines 30-35.

Claim 48 has been amended for clarity of the claimed limitation.

**Support for New Claims**

Claims 49-65 are newly submitted with this amendment.

Claim 49 is supported in the application at page 45, line 8.

Claim 50 is supported in the application at page 35, line 9.  
Claim 51 is supported in the application at page 14, line 10.  
Claim 52 is supported in the application at page 14, line 10.  
Claim 53 is supported in the application at page 29, line 19.  
Claim 54 is supported in the application at page 26, line 33.  
Claim 55 is supported in the application at page 27, line 31.  
Claim 56 is supported in the application at page 33, line 30.  
Claim 57 is supported in the application at page 33, line 31.  
Claim 58 is supported in the application at page 29, line 28.  
Claim 59 is supported in the application at page 30, line 21.  
Claim 60 is supported in the application at page 30, line 30.  
Claim 61 is supported in the application at page 30, line 31-33.  
Claim 62 is supported in the application at page 36, line 7-10.  
Claim 63 is supported in the application at page 30, line 22.

**Claim Rejections 35 USC §112**

Claims 1, 26-48 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Amended claim 1 no longer recites the limitation of a range of “greater than 48 hours.” Similarly, pending claims 26-29, which are dependent on claim 1, do not recite the aforementioned limitation in light of the amendment to claim 1. As such the rejection with respect to claim 1 and claims 26-29 is moot. Finally, since claims 30-47 are cancelled, the rejection is moot with respect to these claims. In light of the foregoing, Applicants respectfully request withdrawal of the rejection.

**Claim Rejections 35 USC §103**

Claims 1, 30 and 43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Peterson (U.S. Patent No. 4,472,394).

Claim 35 was rejected under 35 U.S.C. §103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Peterson (U.S. Patent No. 4,472,394) and further in view of Husmann et al.

Claims 29, 34, 39 and 47 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Peterson (U.S. Patent No. 4,472,394).

In view of the present amendments, applicants respectfully rebut these rejections.

Claims 30, 34, 35, 39, 43 and 47 are cancelled, and the rejections as to these claims are moot.

As amended, claims 1 and claim 29 now recite limitations which distinguish the present invention from the cited prior art. Claim 1 recites a method employing a drug delivery unit having a **volume limitation of between 0.1 to 250 mm<sup>3</sup>** and a therapeutic agent present in (and released from the device in) **nanogram to microgram quantities**. Claim 29 adds a further limitation wherein the therapeutic agent is present in a **quantity of 10 to 40 wt%** of the total weight of the drug delivery unit.

The Manning reference discloses a drug delivery device (HA) loaded with many tens of milligrams of a drug (gentamicin sulfate). For example, at page 9 the dose is disclosed as being 64 mg, and at page 40, Manning states that the drug dose is 40 mg per patient. Peterson discloses an implant containing 27.00 mg of drug (norgestomet) (column 2, line 28).

In contrast the instant invention's claims recite a synthetic controlled release carrier material adapted for delivery of a therapeutic agent in **nanogram to microgram quantities**. Neither Manning et al nor Peterson can be said to suggest the limitations of the claimed invention.

In summary, since Manning et al. and Peterson, alone or in combination, do not teach or suggest the claimed invention, they do not make the invention obvious. Applicants respectfully request withdrawal of the rejections.

**CONCLUSION**

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (408) 864-7435.

The appropriate fee is attached or authorized. If the Commissioner determines that an additional fee is necessary, the Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. **50-1953**.

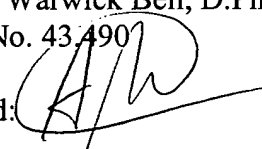
If there are any questions regarding the above, the Examiner is invited to call the undersigned at 408-864-7435.

Respectfully submitted,

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